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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/297,486	06/14/1999	JOHN FRANCIS MARTIN	GJE-30	9834

7590 02/11/2003
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GAINESVILLE, FL 326066669

EXAMINER

SCHNIZER, RICHARD A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/297,486Applicant(s)
Martin et alExaminer
Richard SchnizerArt Unit
1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Nov 25, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____
- Claim(s) objected to: _____
- Claim(s) rejected: 1-9
- Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

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ADVISORY ACTION

At the outset it is noted that the previous Office Action, Paper No. 18, was identified as a non-final Action on the PTO-326, whereas the conclusory paragraph clearly indicated in bold print and capital letters that the Action was made final. In view of the fact that no new grounds of rejection were raised, it is deemed that the finality of the Office Action was proper and clear.

The request for reconsideration has been considered but does not place the application in condition for allowance.

The declaration of Dr. Martin was received with Paper No. 19, and has been considered along with Applicant's arguments.

At pages 3 and 4 of the response, Applicant argues that the specification enables the claimed invention, relying for support on the data presented in the Declaration of Dr. Martin wherein an anastomosis procedure is carried out on pigs, some of which receive an adenoviral vector encoding VEGF while control animals do not. The argument is unpersuasive because the significance of the data is unclear. There is no statistical analysis, the sample size is small, and the results seem to indicate that the treatment may in fact increase intimal hyperplasia over time. See in particular, page 5, first sentence of paragraph 4 which indicates that at day 60 there was an increased degree of intimal proliferation/fibrosis and a reduction in luminal diameter in the groups which received VEGF-D adenovirus, when compared with the controls, and that luminal occlusion occurred only in animals treated with VEGF-D. Finally, because intimal hyperplasia is

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known to occur in about 30% of arterial bypasses after two years (see specification at page 2, lines 10 and 11), it is not clear that an inhibition of intimal proliferation in 50% of individuals at 28 days after surgery is significant at all, particularly in view of the small sample size and the fact that after 60 days intimal proliferation and luminal occlusion increased in VEGF-treated individuals.

Applicant also argues that the rabbit is an art-accepted animal model, relying for support on Strauss(202) and Farb (2001), and noting that Farb indicates that the rabbit iliac model may be the superior animal model to study responses likely to be seen in humans. Applicant is reminded that developments occurring after the filing date of an application are of no significance regarding what one skilled in the art believed as of that filing date. See for example, *in re Wright*, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993). Even if these articles had been published prior to the effective filing date of the instant application (November, 1996), Applicant's arguments would be unpersuasive because no reasoning was presented as to why the findings of Muller (1992), Lafont (1995), Lafont (1998), and Johnson (1999) regarding the physiological differences between various animals and the lack of suitability of small animal models of intimal hyperplasia and restenosis should be cast aside. For these reasons the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
2/8/03